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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

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07/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,651	KANG ET AL.	
	Examiner	Art Unit	
	DEBBIE K. WARE	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

S.N. 10/531,651

ART UNIT 1651

DETAILED ACTION

Claims 1-7 and 9 are pending.

Response to Amendment

The amendment and extension of time filed April 7, 2008, have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-8 (8 now canceled in amendment of April 7, 2008), in the reply filed on July 3, 2007, is acknowledged.

Claim 9 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 3, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7 are rejected for the recitation of "i.e. by antibody test" and "e.g. with immunohistochemcial immunoflourescent methods" because the use of these examples in the claims (note claim 1, specifically) is not permitted because the claims are indefinite as to whether these are claimed features or what? The metes and bounds of the claims can not be determined. Claims 2-7 are rendered vague and indefinite because they depend from claim 1 wherein the problematic recited language occurs at lines 4 and 6. The claims are further rendered vague and indefinite as newly amended for failing to set forth proper antecedent basis for the recitation of "cells" at the last line of the claim. Also the steps for selecting the strain are unclear and the method of producing a product as claimed fails to recite clear and distinct process steps for carrying out the method. For example, it is unclear that a culturing step is being employed by the claimed method. The metes and bounds of the claims can not be determined. Also what is the intended meaning of the language "CD4+ cell recruit - ment". Do the cells of the strain bind with these cells in some type of antibody-like reaction or does it produce them, an explanation is requested as to what the intended mechanism of activity is, by usage of this language in these claims.

Response to Arguments

Applicants apparently do not have the correct set of claims of record, thus, the language remains recited in the claims. Upon indication of any allowable subject matter it is possible that this issue can be remedied by Examiner's Amendment and will be done so at the time allowable subject matter has been indicated, however, at this time this is not applicable because there is no allowable subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **newly cited** Cavadini et al (5968569).

Claims drawn to a method of producing a product for improving immune-function in mammals, comprising selecting a strain of Lactobacillus reuteri that exhibits good

toxin binding and neutralizing effect; and exhibits good CD4+ cell recruitment and formulating the roduct to contain cells of the strain of Lactobacillus reuteri. The product comprises a strain with at least these characteristics and be in the form of a food, tablet, dietary supplement, confectionery, or an oral drug.

Cavadini et al teach a method of producing a product for improving immun-function in mammals comprising a probiotic wherein the probiotic can be Lactobacillus reuteri, see column 1, lines 25-30 and column 3, lines 1 and 22. The probiotic can be encapsulated, column 3, line 30. The probiotic microorganism strain cells are contained in food, column 6, lines 17-19 and column 6, line 37. Also a nutritional or dietary supplement is disclosed, note column 6, line 51. Coatings for the product are disclosed at column 8, line 28, of which pellets (i.e. tablets) are disclosed, see line 45. The probiotic microorgansims can also be in a sugar carrier (i.e. confectionery), note column 2, lines 19 and 24; and also column 5, lines 25-28. Since the disclosed product has the effect of the probiotic microorganism it can contain, such as probiotic bacteria for which can activate the immune functions of a mammal, it can also be in the form of an oral drug, column 1, lines 25-30. The cited disclosure clearly teaches that a probiotic can be selected from a Lactobacillus reuteri microorganism which can be any strain thereof. Also the probiotic microorganism clearly possess immune-improving function and exhibit good neutralizing effects of toxic amine compounds which means that they have an inhibitory effect on toxin binding in the mammals. No disclosure is discussed in terms of the probiotics' effect on CD4+ cell recruitment, however, it is believed by the Examiner to be an inherent feature of the selected probiotic strain because it is

disclosed to have the ability to activate the immune functions of a mammal and also to inhibit production of toxic amine compounds in the mammal.

The claims are considered to be identical to the teachings of Cavadini et al and are, therefore, anticipated by the teachings of the reference. The selected strain of Lactobacillus reuteri disclosed by Cavadini et al will inherently possess at least the characteristics of exhibiting good toxin binding and neutralizing effect; and exhibit good CD4+ recruitment because the probiotic microorganism strains are disclosed to inhibit the growth and activity of putrefying bacteria and hence the production of toxic amine compounds and to activate immune function in a mammal. Lactobacillus reuteri is further disclosed to be a suitable probiotic microorgansim to be contained by the disclosed products which include food, capsules and pellets which are functionally similar to tablets,, dietary supplement, confectionery forms of the product, and an oral drug.

However, in the alternative that there is some difference between the claims and the cited Cavadini et al reference, then such difference is considered to be so slight as to render the claims prima facie obvious over Cavadini et al. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a product for improving immune-function in mammals comprising selecting a strain of Lactobacillus reuteri and formulating the product to contain cells of the strain because the reference clearly teaches that these strains are good probiotics capable of improving immune-function in mammals.

The strains will have to exhibit good toxin binding the neutalizing effect as well as good CD4+ cell recruitment in order to be effective for improvement of immune-function. Also it is disclosed that the inhibitory effect of putrefying bacteria in the mammal also is indicative of inhibiting toxic amine compounds. Therefore, good toxin binding and neutralizing effect are intrinsic to the teachings of the reference and further CD4+ cell recruitment will also be an intrinsic effect of the selected probiotic.

Furthermore, to formulate the probiotic in the form of a food, confectionery, tablet, dietary supplement, oral drug, etc. is an obvious modification at the very least even if these claimed features are not considered to be disclosed. However, in reference to the latter it is believed by the Examiner that these formulations are clearly disclosed, or are at least suggested, by the teachings of the reference.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/
Examiner
1651

/David M. Naff/
Primary Examiner, Art Unit 1657

Deborah K. Ware
July 4, 2008